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| 10/085,731 | 03/01/2002 | Gary K. Michelson | 101.0081-00000 | 8412 |
| 22882 | 7590 | 07/21/2004 | EXAMINER | |
| MARTIN & FERRARO, LLP 1557 LAKE O'PINES STREET, NE HARTVILLE, OH 44632 | | | PRIDDY, MICHAEL B | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3732 | |

DATE MAILED: 07/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/085,731

Applicant(s)

MICHELSON, GARY K.

Examiner

Michael B Priddy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04/30/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-121 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-121 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 04/30/2004.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-121, in the reply filed on 04/30/2004 is acknowledged.

Claim Objections

Claims 1-61 are objected to because of the following informalities: in line 1 of claim 1, "a trailing end" should be --trailing end--; In line 1 of claim 5, --said-- should be inserted between "wherein" and "opening"; In line 1 of claim 29, "opposed" should be deleted; In line 2 of claim 40, --a-- should be inserted between "has" and "height".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 6, 7-11, 13, 16, 19, 20, 23, 24, 33-40, 44, 45, 51-53, 65-68, 70-73, 75, 79, 80, 83, 84, 92-97, 101, 102 and 108-110 rejected under 35 U.S.C. 102(e) as

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being anticipated by Cauthen (U.S. 2003/0135220). Cauthen teaches a spinal implant insertion instrument for spinal interbody prosthesis comprising: a body 12 having a leading end 17 and opposite trailing end 15, said body 12 having a first portion 18 and a second portion 37 in pivotal relationship to one another proximate said leading end 17 between an angled open position and a parallel closed position, said first 18 and second 37 portions having at least in part opposed interior portions 14 being at least in part flat, respectively, said first 18 and second 37 portions defining an opening for providing protected access to the disc space and the adjacent vertebral bodies, said opposed interior portions 14 being adapted to guide therethrough a drill sized to form an implantation space across the disc space and at least in part into the adjacent vertebral bodies; and at least one disc space penetrating extension 20/35 extending from said leading end 17 of said body 12 adapted for insertion at least in part into the disc space, said extension 20/35 having a first portion 20 extending from said first portion 18 of said body, said first portion 20 of said extension having a contact surface adapted to bear against one of the adjacent endplates of the adjacent vertebral bodies, said extension having a second portion 35 extending from said second portion 37 of said body 12, said second portion 35 of said extension having a contact surface adapted to bear against the other of the adjacent endplates of the adjacent vertebral bodies, said contact surfaces of said first 20 and second 35 portions being in pivotal relationship to one another from an insertion position to a deployed position to move the adjacent vertebral bodies apart upon movement of said first 18 and second 37 portions of said body from the open position to the closed position; wherein said opposed interior portions 14 of

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said first and second portions of said body are parallel to one another when said body is in the closed position but angled to one another in the open position; wherein said opening defined by said first and second portions of said body 12 is generally circular but, as set forth in paragraph 0039, may be rectangular; wherein said body 12 has an exterior surface that has opposed upper and lower surfaces oriented toward the adjacent vertebral bodies, respectively, said upper and lower surfaces being at least in part flat; wherein said exterior surface of said body has opposed side surfaces, said side surfaces being at least in part flat; wherein said side surfaces of said exterior surface are parallel to one another; wherein said body has an exterior surface that has a generally circular cross section along at least a portion of the length of said body but may have a rectangular cross section; wherein said extension has a height between contact surfaces and a length sufficient to properly align and distance apart the adjacent vertebral bodies when in the deployed position; wherein said body 12 has an external surface at its leading end and said extension has an external surface that is at least in part coextensive with said external surface of said body 12; wherein said extension has a tapered leading end to facilitate placement of said extension into the disc space when in the insertion position; further comprising an impaction cap 24 adapted to cooperatively engage said trailing end of said body when said body is in the open position; further comprising a lock 26 threadably engaging said trailing end 15 of said body 12 and adapted to cooperatively engage said body 12 when said body 12 is in the closed position to hold said body 12 in the closed position; wherein said body 12 has a height in the range of 6-24mm and said opening defined by said first 18 and second 37

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portions of said body 12 has a height in the range of 6-24mm; further including a reamer (disclosed in line 3 of paragraph 0038) ; further including an implant driver (disclosed in lines 4-5 of paragraph 0039); and further comprising a spinal implant (line 5 of paragraph 0039).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 12, 14, 69, 74 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen. As set forth above, Cauthen discloses the claimed invention except the opening defined by said first and second portions of said body is generally square; and that the exterior surface of the body has a generally square. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct insertion instrument of Cauthen with a rectangular cross section, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing an insertion instrument for a spinal interbody prosthesis. In re Dailey and Eilers, 149 USPQ 47 (1966).

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Claims 21, 41-43, 50, 81, 98-100 and 107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen as applied to claims 23, 45, 62 and 99 in view of the following. Cauthen teaches all of the limitations of the present invention except the contact surfaces have a length greater than one half the depth of the disc space measured from the anterior to the posterior aspect of the adjacent vertebral bodies; the bone removal device has a height in the range of 8-20 mm and a width in the range of 10-25mm; the opening defined by said first and second portions of said body has a width of 10-25 mm; the extension has a combined height when closed in the range of 6-18 mm; and the extension has a length in the range of 12-32 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct these portions of the device of Cauthen such that it had these dimensions, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 46-49 and 103-106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich et al. (U.S. 5,015,255). Cauthen teaches all of the limitations of the present invention except said working device having a working end adapted for insertion into the spine, said working end having at least two cutters selected to create a predetermined surface contour into each of the adjacent vertebral bodies as said working end is moved; said cutters being adapted to simultaneously create predetermined surface contours on the respective end plates of the adjacent vertebral bodies; said working end including a leading edge configured as a bone-cutting surface;

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said cutters are configured to be generally parallel to the surface contour formed in the vertebral body as said working end is moved.

Kuslich et al. teaches a surgical tool with retractable cutting blades to enlarge a cavity on the interior of opposing vertebra bodies and remove degenerative disc material. The surgical tool device having a working end 26 adapted for insertion into the spine, said working end 26 having at least two cutters 40 & 42 selected to create a predetermined surface contour into each of the adjacent vertebral bodies as said working end 26 is moved; said cutters 40 & 42 being adapted to simultaneously create predetermined surface contours on the respective end plates of the adjacent vertebral bodies; said working end 26 including a leading edge configured as a bone-cutting surface; said cutters 40 & 42 are configured to be generally parallel to the surface contour formed in the vertebral body as said working end 26 is moved. It would have been obvious to one of ordinary skill in the art at the time of the present invention to use the surgical tool with retractably cutting blades as taught by Kuslich et al. with the instrument of Cauthen to allow for a large reamed chamber in the diseased tissue of the adjacent vertebra while simultaneously allowing for a small access hole. Such a small access hole avoids interference with other anatomical parts of the patient.

Claims 54-62 and 111-119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen in view of Bianchi et al. (U.S. 2004/0073309). Cauthen teaches all of the limitations of the present invention except said implant comprises ceramic and bone morphogenetic protein and includes a porous material.

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Bianchi et al. teaches an open intervertebral spacer which, in one embodiment, comprises a biphasic calcium phosphate ceramic including tricalcium phosphate and hydroxyapatite (paragraph 0084). In claim 6 Bianchi et al. requires the implant be of a porous material. The spacer of Bianchi et al. has a greater biomechanical strength than bone dowels of the prior art and therefore avoids collapse under the intense cyclic loads of the spine prior to fusion (paragraph 0010). Bianchi et al. also teaches the spacer should include an osteoinductive factor in a pharmaceutically acceptable carrier. This carrier is preferably capable of being resorbed into the body (paragraphs 0085-0087). It would have been obvious to one of ordinary skill in the art at the time of the present invention to use the system of Cauthen to implant the spacer of Bianchi et al. because the spacer offers superior biomechanical properties and avoids failure when implanted in the spine of a patient.

Claims 64 and 121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen in view of Bianchi et al. as applied to claims 53 and 110 above, and further in view of the following. Antimicrobial materials by definition are designed to kill and/or protect against microbes. It would have been obvious to one of skill in the art at the time of the present invention to include one or more antimicrobial materials in the spacer of the combination of Cauther and Bianchi et al. to prevent infection at the surgical site during and after implantation of said spacer.

Claims 63 and 120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen in view of Bianchi et al. as applied to claims 53 and 110 above, and further in view of Gruskin et al. (U.S. 2003/0023209). The combination taught by

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Cauthen and Bianchi et al. teaches all of the limitations of the present invention except the guard in combination with a chemical substance adapted to inhibit scar formation.

Gruskin et al. teaches a method of reducing scar formation at a wound site by contacting the wound site with cross-linked polysaccharide having a positive charge. It would have been obvious to one of ordinary skill in the art at the time of the present invention to apply a cross-linked polysaccharide to the instrument of Cauthen such that it would contact the wound and reduce scar formation to avoid psychological discomfort of the patient postoperatively (paragraph 0009).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-37, 39, 40, 43-45, 50-67, 72, 77-94, 96, 97, 99-102, 108-121 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15, 18-64, 70, 77-100, 102-115 of copending Application No. 10/085,731. Although the conflicting claims are not identical,

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they are not patentably distinct from each other because the difference between the two inventions amounts to the body portions being of a different shape. '731 claims all of the limitations of the present invention except the opposed interior portions of the body being in part flat; the opening defined by said first and second portions of said body being generally square or rectangular; the exterior surface of the body having a generally rectangular or square cross-section; and the body having a generally rectangular or square cross-section.

It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the body claimed in '731 such that except the opposed interior portions of the body being in part flat; the opening defined by said first and second portions of said body being generally square or rectangular; the exterior surface of the body having a generally rectangular or square cross-section; and the body having a generally rectangular or square cross-section, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a guard for use in human interbody spinal surgery. In re Dailey and Eilers, 149 USPQ 47 (1966).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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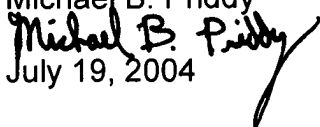
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael B. Priddy whose telephone number is (703) 308-8620. The examiner can normally be reached on Mon.-Fri. 8 a.m. - 5 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael B. Priddy


July 19, 2004